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Attorney Docket No. 22058-544

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Date of Deposit: January 6, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PPLICANTS:

Warne, et al.

SERIAL NUMBER:

0 6 2004

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10/663,264

EXAMINER:

Not Yet Assigned

FILING DATE:

September 16, 2003

ART UNIT:

1614

For:

DELAYED RELEASE FORMULATIONS FOR ORAL

ADMINISTRATION OF A POLYPEPTIDE THERAPEUTIC AGENT

AND METHODS OF USING SAME

Mail Stop IDS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Transmitted herewith for filing in the present application are the following documents:

1. Supplemental Information Disclosure Statement (1 page), in duplicate;

2. Modified Form 1449/PTO (1 page), in duplicate;

3. Copies of Cited References: A12-15; B2-7; and

4. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 22058-544. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted!

David E/Johnson Reg No. 41 Attorney for Applicants

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Date: January 6, 2004

TRA 1866018v1

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Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants make of record the documents listed on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are enclosed.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed required. However, please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 Reference No. 22058-544.

Respectfully submitted,

David A. Johnson, Reg. No. 4/1,874

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Date: January 6, 2004

TRA 1866016v1

Express Mail No. EV 312717335 US Date of Deposit: James 6, 2004

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PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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01/25/01

Yes

Yes

vork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Modified Form 1449/PTO **Application Number** 10/663.264 **Filing Date September 16, 2003** INFORMATION DISCLOSURE **First Named Inventor** Warne STATEMENT BY APPLICANT **Group Art Unit** 1614 **Examiner Name** Not Yet Assigned (use as many sheets as necessary) Attorney Docket Number 22058-544 **U.S. PATENT DOCUMENTS** Cite Issue Date Name of Patentee(s) or Applicant(s) Sub Class Filing Date
If Appropriate Exam U.S. Patent Class Initials No. Document No. A12 4,518,584 85 05/21/85 Mark, et al. 424 A13 5,496,830 283 03/05/96 Shapiro, et al. 514 A14 5,631,219 6 05/20/97 Rosenthal, et al. 514 A15 5,846,958 114 12/08/98 Capizzi, et al. 514 **U.S. PUBLISHED APPLICATION DOCUMENTS** Cite No. U.S. Published Application No. Published Name of Patentee(s) or Applicant(s) Exam Class Sub **Filing Date** Initials **Date** If Appropriate **FOREIGN PATENT DOCUMENTS** Exam Cite **Foreign Patent Document** Name of Patentee(s) or Applicant(s) Date of **Translation** Initials No. Office Number **Publication** Yes **B2** wo 92/04455 GENETICS INSTITUTE, INC. 03/19/92 Yes В3 WO 96/19574 GENETICS INSTITUTE, INC. 06/27/96 Yes **B4** WO 99/37322 GENETICS INSTITUTE, INC. 07/29/99 Yes

	B7	wo	02/22156 A2	GENETICS INSTITUTE, INC.	03/21/02	Yes			
Services			OTHER PR	IOR ART - NON PATENT LITERATURE D	OCUMENTS	TO SEARCH, ALS			
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a copy or the	iis reierence is not provided as it was previously cited by	or submitted to the	e oπice in a prior application,						
Serial No	erial No, filed, and relied upon for an earlier filing date under 35 U.S.C. §120								
continuation, continuation-in-part, and divisional applications).									
Examiner		Date							
Signature		Considered							

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

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